NATIONAL VACCINE ADVISORY COMMITTEE

Report of the Subcommittee on Vaccine Supply
(Dr. Metzgar)

Approved By The Full Committee

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The Subcommittee on Supply was established by Committee Vote on March 10, 1989 as one of the seven areas of immediate Committee concern to be addressed. The terms of reference were published on May 31, 1989, adopted by the Committee on June 15, 1989 and the first full meeting was held on that date. A draft report was issued on June 16. Subsequent discussion by the Committee led to a redraft with questions on three major areas of concern issued on June 28, 1989. The subcommittee received a detailed staff report from Dr. Hinman on August 22 with several detailed questions from Dr. Georges Peter, all of which were discussed in detail at the subcommittee's regular meeting of September 7, 2989.

The subcommittee's meeting of this date resulted in the framework of a report to the National Vaccine Advisory Committee which is herewith submitted for discussion and ratification. The subcommittee recognizes that many issues do not have clear cut definitions but believes that the recommendations reported here provide the framework for action plans to address the major issues.

1. Vaccine definitions

Considerable discussion on the appropriateness and the suitability of definitions used in earlier drafts of this report were carried forward. The subcommittee felt that common definitions, understandable to all, were essential to the subsequent language of the National Vaccine Program. Three categories are recommended:

a) Mandated, licensed vaccines. The definition, by agreement, would include all mandated vaccines whether State mandated or federally mandated. Currently these vaccines are DTP, OPV-IPV, MMR, H flu b and DT.

b) Non-Mandated, licensed vaccines. The definition includes all other licensed vaccines.

c) Non-Mandated-Non-licensed Vaccines. The definition includes all non-licensed vaccines for purposes of identification and discussion.

The subcommittee recognizes that no single definition fulfills all criteria that might be established but suggests that this structure provides a readily identifiable recognition.

2. The subcommittee finds that the current supply of mandated-licensed vaccines and non-mandated licensed vaccines appears to be stable and adequate; however, it is recognized that shortages and supply interruptions may occur, especially in the case where vaccines are produced by single manufacturers.

It is recommended that the National Vaccine Plan, through the Office of the Director, have provisions and procedures for regular monitoring and review to ensure vaccine productive capacity.

3. Although a utilization issue, the assurance of adequate supplies is dependent upon the acceptance and use of vaccines. Certainly there is no greater disincentive to maintaining supply than failure to use the supplies available. No manufacturer will invest in inventory on a non-saleable risk basis.

We believe that the National Vaccine Plan should encompass a program to develop and encourage policies at the Federal, State, and local levels to ensure continued use of vaccines, particularly vaccines used in adults. We believe this should include redefinition of recommendations designed to expand vaccine use in non-high risk groups, such as high density employment environments and a national program of professional and public awareness.

4. The national vaccine stockpile was begun in 1983 and was intended to provide a 6-months supply of mandated vaccines for national needs. The stockpile has been used on five occasions since its inception.

The circumstances concerning the routine administration and maintenance of the national vaccine stockpile as well as the five situations of vaccine shortage were reviewed by the subcommittee.

The subcommittee agrees that the nation's health is considerably better off with the national vaccine stockpile in place than without it. However, the stockpile is a novel public health measure and, now that it has been in place for nearly six years, it is appropriate to reassess its goals and to acknowledge certain "second generation" problems.

Although it was anticipated that a six month supply would be included in the stockpile, this has not yet been attained. Indeed, the subcommittee believed that even a six month supply might not be sufficient. In the interest of extending the supply, the subcommittee recommends that certain questions be pursued: the stability of vaccines, the turn-around time for filling and distribution, the feasibility of stockpiling a portion of vaccine in bulk form.

At present, the stockpile only contains mandated by law for admission to school. The subcommittee believes this is too restrictive and should be broadened. Other vaccines mandated in a minority of States (such as H. influenzae b vaccine) should be included.

Furthermore, there are several other vaccines that are important to the national public health, but whose use is not mandated by law (hepatitis B vaccine, for example). A mechanism should be established to review individual vaccines to determine appropriateness for inclusion in the stockpile.

Lastly, it is concluded that the national vaccine stockpile is an important and essential resource for the National Vaccine Program. As such, it requires reliable and sufficient funding. The precarious nature of its current funding is insufficient and constitutes a hazard to the health of the Nation.

The subcommittee notes with some concern that the Fiscal 1990 budget contains no provisions for funding of stockpile purchases by the Centers for Disease Control (CDC).

5. The subcommittee believes that the effective administration and proper assessment of vaccine supply requires a focused responsibility, preferably within the Office of the Director of the National Vaccine Program.

The responsibility and direction for insuring supply currently is not the responsibility of any one agency, although several agency functions contribute to certain aspects of vaccine supply, i.e., CDC stockpile and purchase contracts including so called traveller's vaccines. The Food and Drug Administration plays a role in testing and release of vaccines.

The subcommittee notes that while there are apparent Department and agency rules of exception provided or inferred in regulations and laws, they are not uniformly interpreted, utilized or implemented and in some cases not recognized.

The subcommittee believes that a centralized responsibility to deal with vaccine supply is a supportable concept. It is also felt that the assignment of this responsibility to the Office of the Director, National Vaccine Program provides clearly recognized focus and is compatible with the goals of the National Vaccine Program and the National Vaccine Plan.

6. In the previous drafts, the subcommittee identified a number of issues which were addressed individually, i.e.,

a) emergency powers relating to the interruption of supply or where emergency supplies are required,

b) the need for a systematic organized plan, administered by the National Vaccine Program to respond to vaccine supply problems,

c) the role of the National Vaccine Advisory Committee and the role of agencies in responding to vaccine supply problems,

d) the manufacturer and supply of non-mandated non-licensed vaccines,

e) The technical problems in licensing vaccines where efficacy data is not obtainable,

f) the acquisition of non-mandated non-licensed vaccines for public use,

g) the assessment of potential vaccine requirements and the identification of potential vaccine shortages before they occur, and

h) stockpile of vaccines of international importance.

The subcommittee suggests that these questions cannot be effectively addressed individually but addressed collectively by a systematic, centrally administered program and would form the basis for an effective response to vaccine supply concerns.

7. Each of the following issues were discussed individually:

a) There are no identified statutory provisions explicitly authorizing FDA or the U.S. Public Health Service to suspend licensing requirements in cases of supply shortage or emergency. The subcommittee believes that the use of such powers would be rare in any event and that liability issues and the requirement to indemnify would be an impediment of significant impact. However, this does not negate the need for contingency plans which should become a part of the strategies of the National Vaccine Plan.

b) The need for a systematic organized plan and its focus of administration has been discussed above. We believe that to accomplish this plan, the direction should be centralized in the Office of the National Vaccine Program in conjunction with the National Vaccine Advisory Committee.

c) The manufacture, supply and license of non-mandated non-licensed products pose special problems.

Each vaccine represents different sets of issues in licensing. Efficacy data may or may not be obtainable and applications may have varying importance in public health measures. There may or may not be a manufacturer of record and negotiations for manufacture and acquisition would be complicated and specialized.

The subcommittee believes that a centralized responsibility would and could effectively address these issues.

8. The issue of liability continues to be a major element in supply of some non-mandated licensed vaccines and all non-mandated non-licensed products. It is recognized that manufacturers have addressed some products through self insurance plans; however, extension of this coverage to some vaccines is usually not practical. The subcommittee suggests that the issue of liability be the subject of continuing study and dialogue but offers no potential solutions to the problem.

9. This issue of manufacture and supply on non-mandated non-licensed vaccines was discussed. It was noted that they Department of Defense contracts with the Salk Institute, Government Services Division, to manufacture such vaccines for the U.S. Military. The subcommittee believes that, where such vaccines are required, current practices of contract manufacturing with licensed manufacturers would be appropriate when possible. However, the establishment of a government vaccine manufacturing capability should be considered as an option. It would appear that regulations would allow for such an option.

The subcommittee is indebted to those groups who have previously examined vaccine supply issues, particularly the National Vaccine Study group, the Institute of Medicine and the Centers for Disease Control. Clearly, the observations made and the issues addressed remain valid and served as the basis for subcommittee discussions.

The Subcommittee believes this is a unique opportunity to recognize and implement recommendations of long standing and importance to vaccine supply. It was agreed that additional consideration of the Government's role in encouraging competition to ensure the continued supply of safe and effective vaccines will require further discussion about the interplay among often contradictory issues of 1) maintenance of an stable research/manufacturing base, 2) vaccine pricing, 3) vaccine supply, 4) incentives for innovation, and 5) prospects for internationalization of licensing standards.